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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,772	05/16/2000	FRANCIS PETIT	146.1339	6484

5487 7590 08/28/2006

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EXAMINER	
RILEY, JEZIA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/554,772	PETIT ET AL.	
	Examiner	Art Unit	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 11-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 11-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Remarks

1. Applicants' arguments, filed on 7/10/06, have been approved and entered. They have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leadlay et al. (USPN 6,437,151) in view of Hayes et al. (Comp. Biochem, Physiol. Vol. 113B, No2, pp. 349-353, 1996).

Leadlay teaches a method of treating a human with atherosclerosis (e.g., a platelet aggregating condition), in which *Chlamydia pneumoniae* appeared to play a role in the development of the atherosclerosis, using ketolides (see col. 4-11 and Examples 16-18, especially col. 11, lines 11-14). Accordingly, because Leadlay teaches ketolides are active against a platelet aggregating condition in which *Chlamydia pneumoniae* appeared to play a role (i.e., ketolides possess anti-infectious properties against *Chlamydia pneumoniae*), it is an inherent property of the ketolides of Leadlay that the ketolides prevent or inhibit platelet aggregation.

Regarding Claim 12, Leadlay teaches the daily dosage is between 0.1-100 mg/kg (col. 12, lines 13-15).

Hayes et al. discloses that one of the essential components of atherogenesis is platelet aggregation. The aggregation process enhances thrombus formation and clotting further accentuating aggregation.

Therefore inherently, Leadlay teaches ketolides that are active against a platelet aggregating condition in which *Chlamydia pneumoniae* appeared to play a role in the development of atherosclerosis in man. (i.e., ketolides possess anti-infectious properties against *Chlamydia pneumoniae*), it is an inherent property of the ketolides of Leadlay

prevent or inhibit platelet aggregation. Therefore treating atherosclerosis will inherently inhibit platelet aggregation.

5. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masamune et al. (USPN 6,025,350) in view of Hayes et al. (Comp. Biochem, Physiol. Vol. 113B, No2, pp. 349-353, 1996)

Masamune teaches a method of treating a human with atherosclerosis, in which *Chlamydia pneumoniae* appeared to play a role in the development of the atherosclerosis, using ketolides (see col. 1-15 and 65-72, especially col. 8, lines 41-43 Regarding Claim 10, Masamune teaches the daily dosage is between 0.2-200 mg/kg (col. 35, lines 20-27).

Hayes et al. discloses that one of the essential components of atherogenesis is platelet aggregation. The aggregation process enhances thrombus formation and clotting further accentuating aggregation.

Therefore inherently, Masamune teaches that ketolides are active against a platelet aggregating condition in which *Chlamydia pneumoniae* appeared to play a role in the development of atherosclerosis in man. (i.e., ketolides possess anti-infectious properties against *Chlamydia pneumoniae*), it is an inherent property of the ketolides of Masamune prevent or inhibit platelet aggregation. Therefore treating atherosclerosis will inherently inhibit platelet aggregation.

6. Claims 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shor et al. (USPN 5,424,187), in view of Agouridas et al. (USPN 5,747,467) in view of Hayes et al. (Comp. Biochem, Physiol. Vol. 113B, No2, pp. 349-353, 1996).

Shor teaches methods for treating arterial chlamydial granulomatous disease using anti-*Chlamydia pneumoniae* agents, such as erythromycins (see abstract; col. 2, line 67 to col. 3, line 10; col. 6, lines 49-56; col. 12, lines 40-54, for example). Shor further teaches that atherosclerotic lesions (i.e., atherosclerosis, a platelet aggregating condition) result from chlamydial granulomatous disease (see col. 7, lines 22-44 and Examples 2-8). Accordingly, Shor teaches treating a human with atherosclerosis, in which *Chlamydia pneumoniae* appeared to play a role in the development of the atherosclerosis, using erythromycins.

While Shor teaches the treatment using anti-*Chlamydia pneumoniae* agents, such as erythromycins, Shor does not teach using a ketolide, which is an erythromycin derivative.

However, Agouridas teaches ketolides are anti-*Chlamydia pneumoniae* agents (see col. 5). Specifically, Agouridas teaches a method of combating Chlamydia infections in warm-blooded animals including humans comprising, administering to warm-blooded animals an effective amount of a ketolide or its non-toxic, pharmaceutically acceptable acid addition salts (col. 5, ln. 33-38).

Regarding Claim 12, the reference teaches that the usual daily dose is 1.5 to 6 mg/kg, and therefore, provides a range equivalent to the range provided in claim 10

(col. 5, lines 40-42). For example, if the daily dose was at 4mg/kg, and an individual to whom the ketolide was administered weighed 100 kg, then 400 mg would be administered to said individual per day.

Regarding Claims 13-17, Agouridas teaches the claimed ketolides (see cols. 1-5 and Example 3).

Hayes et al. discloses that one of the essential components of atherogenesis is platelet aggregation. The aggregation process enhances thrombus formation and clotting further accentuating aggregation. Therefore treating atherosclerosis will obviously inhibit platelet aggregation.

Accordingly, in view of the teachings of Agouridas and Hayes, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Shor so as to have used the ketolides of Agouridas. One of ordinary skill in the art would have been motivated to modify the method of Shor, by using a ketolide of Agouridas, in order to have achieved the benefit of providing an effective method of treating a human with atherosclerosis, in which *Chlamydia pneumoniae* appeared to play a role in the development of the atherosclerosis, and therefore to have prevented or inhibited platelet aggregation. The ketolides of Agouridas would have provided Shor with the anti-*Chlamydia pneumoniae* agent necessary for inhibiting the granulomatous process, and therefore, providing an effective therapeutic treatment (of preventing or inhibiting platelet aggregation) for a patient suffering from atherosclerosis (a platelet aggregating condition).

7.. Claims 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shor et al. (USPN 5,424,187, previously cited), in view of Agouridas et al. (USPN 5,635,485)) in view of Hayes et al. (Comp. Biochem, Physiol. Vol. 113B, No2, pp. 349-353, 1996).

Shor teaches methods for treating arterial chlamydial granulomatous disease using anti-*Chlamydia pneumoniae* agents, such as erythromycins (see abstract; col. 2, line 67 to col. 3, line 10; col. 6, lines 49-56; col. 12, lines 40-54, for example). Shor further teaches that atherosclerotic lesions (i.e., atherosclerosis, a platelet aggregating condition) result from chlamydial granulomatous disease (see col. 7, lines 22-44 and Examples 2-8). Accordingly, Shor teaches treating a human with atherosclerosis, in which *Chlamydia pneumoniae* appeared to play a role in the development of the atherosclerosis, using erythromycins.

While Shor teaches the treatment using anti-*Chlamydia pneumoniae* agents, such as erythromycins, Shor does not teach using a ketolide, which is an erythromycin derivative.

However, Agouridas teaches ketolides are anti-*Chlamydia pneumoniae* agents (see col. 6). Specifically, Agouridas teaches a method of combating Chlamydia infections in warm-blooded animals including humans comprising, administering to warm-blooded animals an effective amount of a ketolide or its non-toxic, pharmaceutically acceptable acid addition salts (col. 6, ln. 55-59).

Regarding Claim 12, the reference teaches that the usual daily dose is 1.5 to 6 mg/kg, and therefore, provides a range equivalent to the range provided in claim 10 (col. 5, lines 40-42). For example, if the daily dose was at 4mg/kg, and an individual to whom the ketolide was administered weighed 100 kg, then 400 mg would be administered to said individual per day.

Regarding Claims 13-17, Agouridas teaches the claimed ketolides (see cols. 1-5 and Example 3).

Hayes et al. discloses that one of the essential components of atherogenesis is platelet aggregation. The aggregation process enhances thrombus formation and clotting further accentuating aggregation. Therefore treating atherosclerosis will obviously inhibit platelet aggregation.

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Accordingly, in view of the teachings of Agouridas and Hayes, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Shor so as to have used the ketolides of Agouridas. One of ordinary skill in the art would have been motivated to modify the method of Shor, by using a ketolide of Agouridas, in order to have achieved the benefit of providing an effective method of treating a human with atherosclerosis, in which *Chlamydia pneumoniae* appeared to play a role in the development of the atherosclerosis, and therefore to have prevented or inhibited platelet aggregation. The ketolides of Agouridas would have provided Shor with the anti-*Chlamydia pneumoniae* agent necessary for inhibiting the granulomatous process, and therefore, providing an

effective therapeutic treatment (of preventing or inhibiting platelet aggregation) for a patient suffering from atherosclerosis (a platelet aggregating condition).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thursday, August 24, 2006

/JEZIA RILEY/
PRIMARY EXAMINER